

Application No. 10/797,481

### REMARKS

Claims 21-24 and 28-36 are pending. Claim 21 has been amended. The specification literally supports the amendment of claim 21, for example, at page 1, lines 27-31. No new matter is introduced.

Additionally, the specification has been amended to change "reticular" to "articular." "Reticular" means dermal, relating to the skin, and "articular" means of or relating to a joint. Because the application deals with joints, we find that the correction from "reticular" to "articular" is obvious and does not constitute new matter.

All of the pending claims stand rejected. Applicant respectfully request reconsideration of the rejection based on the following comments.

### Telephonic Interview

Applicant thanks Examiner Michael Priddy for the telephonic interview conducted on September 11, 2007 with Applicant's undersigned representative. Examiner provided useful insight.

Claims 21 and 31 were discussed. Examiner Priddy maintained the position held by former Examiner Annette Reimers in the Office Action dated August 24, 2007. Examiner Priddy indicated that Applicant's invention is different from the Cain invention based on how the immobilization/fusion element is inserted.

Regarding the limitation in claim 21 "...inserting an immobilization/fusion element into the opening of the sacroiliac joint between the ilium and the sacrum..." Examiner appears to believe that the Cain reference discloses an opening in the sacroiliac joint created by inserting an immobilization/fusion element across the ilium and sacrum. Examiner also appears to believe that the Cain reference discloses an opening because the sacroiliac joint is the opening. While

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agreement was not reached, it was clarified that the Examiner and Applicant disagreed on the scope of the particular wording.

Rejection under 35 U.S.C. § 102(b) by Cain

The Examiner rejected claims 21-23, 28, 29, 32, 33, 35 and 36 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,334,205 to Cain (Cain). In the "Response to Arguments," Examiner Reimers asserted: "Although as pointed out by applicant, the screws of the Cain reference are placed across the sacroiliac (SI) joint, the screws are also being placed into the opening of the SI joint between the ilium, 56, and the sacrum, 54 (see figure 5)." With all due respect, this is simply incorrect. Applicant respectfully disagrees with the Examiner's claim construction because it does not reflect the broadest reasonable interpretation in light of the specification. Claim 21 clearly recites a configuration that is patentably distinct from that of the Cain reference, which discloses placement of screws **through** the ilium and sacrum bones. Also, to advance prosecution of the application, Applicant has amended claim 1 for further clarification, although Applicant respectfully maintains that the Examiner's interpretation is not reasonable.

Claim 21 recites "...inserting an immobilization/fusion element into the opening of the sacroiliac joint along the crack of the joint or extra-articular recess between the ilium and the sacrum..." This language is clear. The immobilization/fusion element initially enters the sacroiliac joint via the opening located between the ilium and the sacrum. This configuration distracts the joint and places tension on the ligaments holding the joint together. Please note Fig. 3 of the instant application, which is a rear view of a pelvis. In Fig. 3, a screw is placed into the opening of the sacroiliac joint (darkened area) between the ilium (on one side) and the sacrum (on the other side).

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Claims must be interpreted in light of the specification, and that interpretation cannot be inconsistent with the specification. See MPEP 2111 ("The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.") and 2111.01 ("This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification."). The Office Action's use of Cain reflects an interpretation that is simply not the broadest reasonable interpretation to a person of ordinary skill in the art in light of the specification. In other words, the rejection is based on an unreasonable construction of the claim.

Cain fails to disclose **inserting an immobilization/fusion element into the opening of the sacroiliac joint between the ilium and the sacrum**. Instead, Cain discloses inserting screws **through the ilium and across the ilium and the sacrum via a hole drilled through the bones**. When the hole is drilled across the joint, a portion of the bones and the joint at the hole are removed.<sup>1</sup> When the screws are inserted into the hole through the bones, the screws initially penetrate and directly access the ilium **not the opening of the sacroiliac joint between the ilium and the sacrum**. The screws begin their journey into the joint **across through the ilium and the sacrum not between the ilium and the sacrum**. The screws replace that removed portion of the joint and do not go into the joint. More specifically, **the opening for the Cain implant is NOT between the bones since the bone has been removed at the point where the hole was drilled**. This configuration of the screw compresses the joint and removes tension from the ligaments, in contrast with the configuration claimed by Applicant. Applicant's claim requires that immobilization/fusion element be inserted into the opening of the sacroiliac joint between the ilium and the sacrum. Cain clearly fails to meet this limitation.

As discussed above, "the opening" provides the immobilization/fusion element direct access into the sacroiliac joint without initially penetrating either the ilium or the sacrum. The

<sup>1</sup> The joint is formed by the interface of the bones. According to Webster's Collegiate Dictionary, a joint is "the point of contact between elements of an animal skeleton with the parts that surround and support it."

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claim recites "the opening" when the claim contains no earlier recitation of an opening because "the opening" is an inherent element of the sacroiliac joint between the ilium and the sacrum.<sup>2</sup> A drilled hole cannot constitute "the opening" because it is not an inherent element of the sacroiliac joint but an unnatural element created into the sacroiliac joint. The claim also clearly recites two distinct elements—"the opening of the sacroiliac joint."<sup>3</sup> "[T]he opening" is not the same element as "the sacroiliac joint" but part of "the sacroiliac joint." Accordingly, "the opening of the sacroiliac joint" cannot constitute the entire sacroiliac joint. "[T]he opening of the sacroiliac joint" is also not the intersection between the sacroiliac joint and ilium because these intersections do not provide an exposed opening by which the screw can initially penetrate and directly access the sacroiliac joint. The ilium presents itself as an obstacle to a directly accessible entrance into the sacroiliac joint in forming the intersection with the joint. Claim 21 clearly requires that "the opening" be an exposed, natural opening by which the immobilization/fusion element can initially penetrate and directly access the sacroiliac joint. Cain clearly fails to meet this limitation.

Cain clearly fails to *prima facie* anticipate claim 21. Accordingly, claim 21 and its dependent claims 22-24 and 28-36 should be allowed. While Applicant does not acquiesce with respect to any of the specific issues surrounding the dependent claims, these issues are presently moot in view of the issues presented above.

<sup>2</sup> Both the MPEP and Federal Circuit case law support this interpretation of "the opening" as an inherent element of the sacroiliac joint. MPEP 2173.05(c) states: "Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation 'the outer surface of said sphere' would not require an antecedent recitation that the sphere has an outer surface. See *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001) (holding that recitation of 'an ellipse' provided antecedent basis for 'an ellipse having a major diameter' because '[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter')." "

<sup>3</sup> It would be improper to interpret the sacroiliac joint as the opening because it would render the claim indefinite by referring to the same element by two names in the claim.

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Claim 35

Examiner failed to address claim 35, which recites "[t]he method of claim 21 wherein the immobilization/fusion element has a central channel and is inserted over a guide pin." It does not appear that Cain discloses an immobilization/fusion element with a central channel at all. Cain does not appear to *prima facie* anticipate claim 35.

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Rejection under 35 U.S.C. § 103(a) over Cain in view of Bowman et al.

The Examiner rejected claims 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent 4,950,270 to Bowman et al. (Bowman). As discussed above, Cain fails to disclose or suggest the limitations of claim 21 as amended. Bowman fails to remedy the deficiencies of Cain. Specifically, Bowman fails to disclose or suggest "...inserting an immobilization/fusion element into the opening of the sacroiliac joint along the crack or extra-articular recess of the joint between the ilium and the sacrum..." Thus, the combined teachings of these references does not teach this feature of the presently claimed invention. The references alone or combined do not render Applicant's claimed invention *prima facie* obvious.

Applicant does not acquiesce with respect to the specific assertions regarding the features of these claims, but these issues are rendered moot in light of the discussion above.

Rejection under 35 U.S.C. § 103(a) Over Cain

The Examiner rejected claim 34 under 35 U.S.C. § 103(a) as being unpatentable over Cain.

Examiner failed to provide a reason why a person of ordinary skill would modify Cain to provide an immobilization/fusion element without threads. Examiner also did not provide a secondary reference disclosing this feature. Specifically, Examiner asserted that "it would have been a matter of design choice to one skilled in the art at the time the invention was made to construct the immobilization/fusion element without any threads, since applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purposes of providing an immobilization/fusion element of the joint." For the SI joint, the forces applied by the ligaments as discussed in the application would stabilize the fused joint with a non-threaded

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implant even though such an approach would not be generally suitable for immobilization of other joints or orthopedic structures.

As stated in MPEP 2142: "The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." Here, Examiner has shifted that initial burden to the Applicant by suggesting that Applicant has the responsibility to present evidence of nonobviousness. As stated in the MPEP, Applicant is only obligated to submit evidence of nonobviousness only when the Examiner presents a *prima facie* case of obviousness, and the Examiner has not met their burden.

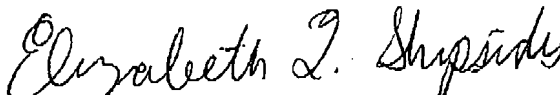
Even with the advent of the Supreme Court decision KSR, the USPTO has emphasized that "in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." Here, Examiner has failed to provide a reason why one would replace the screw of Cain with an unthreaded immobilization/fusion element.

#### CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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